REMARKS

Claims 1, 3, 8-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Silverman et al. (U.S. Patent No. 6,251,063) in view of Astarita (U.S. Patent No. 6,228,059) in further view of Stack (U.S. Patent Publication No. 2001/0051822). Claims 4 and 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Silverman et al. in view of Astarita in view of Stack as applied to Claim 3, and further in view of Kikawada (U.S. Patent No. 5,637,075). Claims 6 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Silverman et al. in view of Astarita in view of Stack as applied to Claim 1, and further in view of Morrison (U.S. Patent No. 4,609,370). Claims 12-15 are rejected under 35 U.S.C. 102(b) as being unpatentable over Silverman et al. Reconsideration of all claims is respectfully requested.

Silverman et al. disclose a method for treating wall forming gastrointestinal tract. Specifically, apparatus or medical device 21 shown therein includes a probe member or probe 22 having an optical viewing device 23. A needle assembly 26 is slidably carried by probe 22. See Column 4, lines 10-14. Probe 22 includes a flexible elongate tubular member or insertion tube 31 having proximal and distal extremities 31a and 31b and a distal face 32. See Column 4, lines 17-23. A working passageway or channel 51 is further provided in insertion tube 31 and extends to a side port 52 formed in handle 33. Column 4, lines 47-49. Needle assembly 26 includes a needle member or needle 61 having a proximal end portion 61a and a distal end portion 61b and an optional sleeve member or sleeve 62 having a proximal end portion or extremity 62a and a distal end portion or extremity 62b. Sleeve 62 and the needle 61 are slidable relative to each other in a longitudinal direction. Needle 61 and sleeve 62 can be slidably disposed within working channel 51 and side port 52 of insertion tube 31 and each have a length so that when distal end portions 61b and 62b are extending from distal extremity 31b of the insertion tube 31 or otherwise in the vicinity of distal face 32, proximal end portions 61a and 62a are accessible at side port 52. See Column 4, line 59 – Column 5, line 15.

As was previously discussed in Applicant's prior response, dated July 18, 2007, Astarita discloses a locking device for use in a trocar inserted into a body cavity. The locking portion may include internal threads formed only on a head, a cam operated element, resilient fingers, a collet-type locking device, or a frictional detent or opening, quickly moved into a locking position against any type of instrument passing through the trocar into the body cavity. The portion of the locking device contacting the instrument must be sized and dimensioned to

provide a firm grip in the locking position, without damaging or marring the instrument against which it is locked. See Abstract.

Stack et al. discloses a stent delivery system used to provide accurate deployment of an self-expanding stent into a target site in a patient's body lumen. Pg. 3, paragraph [0023]. One preferred embodiment of a stent delivery system includes an elongated catheter made up of an inner tubular member which extends within an outer tubular member in a coaxial arrangement. Pg. 3, paragraph [0024]. In a preferred embodiment of the present invention, the inner tubular member is made with three (3) coaxial layers of materials. The inner most layer is the guide wire lumen which runs the entire length of the catheter body. A second layer of the inner tubular member is composed of a proximal portion made from stainless steel hypotube and a distal reinforcing portion which can be made from a material with high compressive strength such as polyetheretherketone (PEEK). The outermost part of the inner tubular member is a thin layer shrink tubing. Pg. 3, paragraph [0026].

According to Stack et al., the application of tensile force to the shaft of the outer tubular member 22 and restraining sheath 29 during stent deployment creates an equal and opposite compressive force on the inner tubular member 21. For the restraining sheath 29 to retract (via the movement of the pull-back handle 27) without causing the rest of the delivery catheter 14 to buckle, the inner tubular member 21 must possess sufficient column strength to prevent buckling or deformation. Otherwise, buckling or deformation to the inner tubular 21 can cause the distal end 20 of the delivery catheter 14 to move within the artery, causing inaccurate deployment of the stent. Therefore, the second layer of the inner tubular member may be comprised of tubular elements which possess sufficient rigidity to prevent unwanted buckling or deformation, yet are flexible enough to track along the torturous anatomy to the target site. Pg. 5, paragraph [0049].

Claim 1 is patentable by calling for an injection device for use with a probe of the type set forth therein including a needle assembly slidably disposed in the tubular member, the tubular member and needle assembly having respective proximal and distal extremities, the distal extremity of the needle assembly being provided with a needle and being extendable from the distal extremity of the tubular member and means carried by the proximal extremities of the tubular member and needle assembly for locking the proximal extremity of the needle assembly relative to the proximal extremity of the tubular member, the needle assembly having a column strength when locked within the tubular member so as not to buckle during puncture of the tissue

by the needle and thus limit retraction of the needle assembly relative to the tubular member during puncture of the tissue and provide substantially one-to-one movement between the proximal and distal extremities of the needle assembly.

As the Examiner knows, to establish a proper prima facie case of obviousness, there must be some suggestion or motivation, either in the cited references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify or combine the cited reference relied upon by the Examiner to arrive at the claimed invention. Second, there must be a reasonable expectation that the suggested modification or combination would be successful. Finally, the prior art reference (or references when combined) must teach or suggest each and every limitation of the rejected claims. The teaching or suggestion to make the claimed modification or combination and the reasonable expectation of success must both be found in the prior art, and not based upon in the applicant's disclosure. M.P.E.P. §706.02. Applicant respectfully submits that a prima facie obviousness has not been established and the invention recited in the instant claims is patentable over the cited references.

Contrary to the assertion of the Examiner, there is no disclosure in Silverman et al., Astarita and Stack et al. that these references be combined in the manner suggested by the Examiner.

As suggested by the Examiner, Silverman et al. does not disclose locking the needle assembly in the tubular member. Instead, the Examiner relies on Astarita for this feature. However, as discussed above Astarita discloses a locking device for use in a trocar inserted into a body cavity. As is well known, a trocar is commonly used as a means for introduction of laparoscopic hand instruments, such as scissors or graspers, to perform laparoscopic surgery. There is no disclosure in Astarita that the locking device therein would be suitable for use with a needle assembly, let alone to lock the proximal extremity of the needle assembly relative to the proximal extremity of the tubular member.

The Examiner further suggests that Silverman et al. and Astarita do not disclose a "second tubular member to have sufficient column strength to prevent buckling and provide substantially one-to-one movement between the proximal and distal extremities of the second tubular member." See Office Action pg. 3. Instead, the Examiner relies on Stack for this feature. Stack et al., as detailed above, disclose that the inner tubular member is made with three (3) coaxial layers of materials. The second layer of the inner tubular member is composed of a

proximal portion made from stainless steel hypotube and a distal reinforcing portion which can be made from a material with high compressive strength, and may be comprised of tubular elements which possess sufficient rigidity to prevent unwanted buckling or deformation, yet are flexible enough to track along the torturous anatomy to the target site. Stack does not disclose a needle assembly having a column strength when locked within the tubular member so as to not buckle during puncture of the tissue and provide substantially one-to-one movement between the proximal and distal extremities of the needle assembly. (emphasis added)

A physician performing a procedure with the device of Silverman et al., which is directed to treating the gastrointestinal tract, would not look to a device or assembly of Astarita or Stack et al. without relying on hindsight in view of Applicant's disclosure. Specifically, a physician would not look to a means for preventing the insertion of tools into the body cavity, as shown in Astarita, for a means to accomplish locking of the proximal extremities of a needle assembly relative to a proximal extremity of the tubular member. Likewise, a physician would not look to a stent deployment method and device as shown in Stack et al., which is designed to prevent movement of the stent during deployment, to arrive at a needle assembly locked within a tubular member having a column strength so as to not buckle during puncture of tissue and provide substantially one-to-one movement between the proximal and distal extremities of the needle assembly. In view of the foregoing, there is no motivation or suggestion in the references, or in the art to successfully combine these references to arrive at Applicant's claimed invention.

Even if Silverman et al. Astarita and Stack et al. are combined in the manner suggested by the Examiner, such combined references do not disclose means carried by the proximal extremities of the tubular member and needle assembly for locking the proximal extremity of the needle assembly relative to the proximal extremity of the tubular member, the needle assembly having a column strength when locked within the tubular member so as not to buckle during puncture of the tissue by the needle and thus limit retraction of the needle assembly relative to the tubular member during puncture of the tissue and provide substantially one-to-one movement between the proximal and distal extremities of the needle assembly.

Increasing the accuracy in placing implants by use of a needle is an important feature of the invention. As discussed in the disclosure of the present application, enhancing the placement accuracy of the needle serves to inhibit damage to the mucosal layer and other adjacent muscle layers from improperly placed material. Page 17, lines 13-15. Specifically, the limiting of the

longitudinal travel or retraction of needle, which is carried by the needle assembly, relative to tubular member permits greater accuracy in the placement depth of the needle in the targeted tissue, thus facilitating relatively consistent puncture depths between injection sites. See Page 20, lines 24-26. Since contraction has been limited, as claimed, by the increased column strength of the needle assembly when locked within the tubular member, the amount of advancement of needle into the probe translates essentially one-to-one with the amount that needle is advanced into the tissue. See Page 20, lines 29-33. Such an improvement is not disclosed in Silverman et al., Astarita, or Stack et al.

In view of the foregoing, Applicant respectfully requests withdrawal of the 103 rejection of Claim 1.

Claims 2-11 depend from Claim 1 and are patentable for the same reasons as Claim 1, and by reason of the additional features called for therein.

Claim 12 is patentable by calling for an injection device of the type set forth therein, and in particular an injection device having a first tubular member adapted for use with the probe and having a diameter for permitting insertion of the first tubular member into the passageway of the probe, the first tubular member having a proximal extremity with a proximal opening and a distal extremity, a second tubular member extending through the proximal opening of the first tubular member and being slidably disposed in a lumen of the first tubular member and having a distal extremity with a needle that is extendable from the distal extremity of the first tubular member, the proximal extremity of the first tubular member having a port distal of the proximal opening, a reservoir of the biocompatible solvent coupled to the port for clearing any of the biocompatible composition that clogs the first tubular member distal of the port.

The Examiner argues Silverman discloses an injection device comprising a probe 22, a first tubular member 31 insertable into the probe, a second tubular member 62 slidable within the first tubular member, the second tubular member being provided with a needle 61. See Office Action, pg. 2. The Examiner recites that "needle 61 has a bevel (Col. 5, lines 20-25)." See pg. 2 of Office Action. It is unclear why the Examiner cites this bevel as a bevel is not claimed.

Applicant's claimed invention, as set forth in Claim 12, includes a first tubular member having a proximal extremity with a proximal opening, and the proximal extremity of the first tubular member has a port distal of the proximal opening. Using the Examiner's reasoning,

insertion tube 31 must therefore have a proximal extremity with a proximal opening and the proximal extremity of the insertion tube 31 must also have a port distal of the proximal opening. A working passageway or channel 51 is provided in insertion tube 31 and extends to a side port 52 formed in handle 33. Thus, side port 52 would be considered the "proximal opening". Insertion tube 31 of Silverman et al., however, does not also have a port distal of this proximal opening 52. See FIG. 1 of Silverman et al. Accordingly, Silverman et al. does not disclose Applicant's claimed invention, as set forth in Claim 12.

Claims 13-15 depend from Claim 12 and are patentable for the same reasons as claim 12 and by reason of the additional features called for therein.

In view of the foregoing, it is respectfully submitted that the claims of record are allowable and that the application should be passed to issue. Should the Examiner believe that the application is not in a condition for allowance and that a telephone interview would help further prosecution of this case, the Examiner is requested to contact the undersigned attorney at the phone number below.

Respectfully submitted,

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